K081614

SEP - 5 2008

# 510(k) Summary
# for the Interbody Innovation Zeus Intervertebral Fusion Devices

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the Interbody Innovation Zeus Intervertebral Fusion Devices.

Date Prepared: June 5, 2008

1. **Submitter:**
Interbody Innovations
303 Veterans Park Lane, Suite 1101
Midland, TX 79705

**Contact Person:**
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Interbody Innovation Zeus Intervertebral Fusion Devices
**Common Name:** intervertebral body fusion device
**Classification Name:** intervertebral body fusion device - cervical
Intervertebral body fusion device - lumbar
21 CFR section 888.3080
ODP/MAX
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
The Interbody Innovations Zeus Intervertebral Fusion Devices are substantially equivalent to similar previously cleared cervical and lumbar intervertebral body fusion devices.

4. **Description of the device:**
The Zeus Small Cervical Cage was developed as an intercorporal implant for anterior cervical spondylodesis. The top view is trapezoidal with a trapezoidal window for bone graft. The Zeus Cervical Cage has a flat top and bottom.

The Zeus Large/Extra Large Lumbar Cage was developed as an implant for the posterior stabilization of the lumbar spinal column using an Anterior Lumbar Interbody Fusion (ALIF) technique. To eliminate migration, ridges are incorporated on both the superior and inferior surfaces. Two large windows allow bony growth to form.

The Zeus Curved Large Lumbar Cage was developed as an implant for the posterior stabilization of the lumbar spinal column using a Transforaminal Lumbar Interbody Fusion (T-LIF) technique. The Zeus Curved implant has ridges on both its inferior and superior surfaces to prevent migration, and two large graft windows which help facilitate bony integration. It is a curved shape to facilitate insertion using a T-LIF approach.

The Zeus Straight Lumbar Cage was developed as an implant for the posterior stabilization of the lumbar spinal column using a Posterior Lumbar Interbody Fusion (PLIF) technique and is used in pairs. The Zeus Straight implant incorporates ridges on both its superior and inferior surfaces to help eliminate migration. A large rectangular graft space help facilitate bony integration once implanted..

**Materials:**
PEEK-OPTIMA LT1 polymer (ASTM F2026 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications)

5. **Intended Use:**
Zeus Small Cervical Cage s are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is

defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Zeus Cervical Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. Zeus Cervical Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Zeus Lumbar Cages are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Zeus implants are to be used with autogenous bone graft and implanted via an anterior/transforaminal/posterior approach. The Zeus Lumbar Cages are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. **Comparison of the technological characteristics of the device** to **predicate and legally marketed devices:**
   The Interbody Innovations Zeus Intervertebral Fusion Devices have the same indications and material, and similar designs as previously cleared devices.

7. **Summary of Non-clinical Tests**
   Tests performed according to ASTM F2077/F2267 indicate that the Interbody Zeus Innovations Intervertebral Fusion Devices meet required mechanical strengths. Some of the predicate devices have a different geometry than the Interbody Innovations Zeus Intervertebral Fusion Devices and do not have some test results reported in their PMA summaries, therefore, additional acceptance values for testing have been utilized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Interbody Innovations, LLP
% Mr. J.D. Webb
The Orthomedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

Re: K081614
Trade/Device Name: Zeus Small Cervical Cage, Zeus Anterior Lumbar Cage, Zeus Curved Lumbar Cage, Zeus Straight Lumbar Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: June 5, 2008
Received: June 9, 2008

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K081614

Device Name: Zeus Small Cervical Cages

Indications for Use:

Zeus Small Cervical Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Zeus Cervical Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. Zeus Cervical Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

| Prescription Use X<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 807 Subpart C) |
|---|---|---|

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Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR MNM

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080614

# Indications for Use

510(k) Number (if known): K081614

Device Name: Zeus Anterior Lumbar Cage

Indications for Use:

The Zeus Anterior Lumbar Cage is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Zeus implants are to be used with autogenous bone graft and implanted via an anterior approach. The Zeus Anterior Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

| Prescription Use X<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 807 Subpart C) |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number K080614

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# Indications for Use

510(k) Number (if known): K081614

Device Name: Zeus Curved Lumbar Cage

Indications for Use:

The Zeus Curved Lumbar Cage is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Zeus implants are to be used with autogenous bone graft and implanted via a transforaminal approach. The Zeus Curved Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

| Prescription Use X (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 807 Subpart C) |
|---|---|---|

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**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K081614

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# Indications for Use

510(k) Number (if known): K080614

Device Name: Zeus Straight Lumbar Cage

Indications for Use:

The Zeus Straight Lumbar Cage is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Zeus implants are to be used with autogenous bone graft and implanted via a posterior approach. The Zeus Straight Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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510(k) Number K080614

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